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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2021-0077]

International Sanitary and Phytosanitary Standard-Setting Activities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with legislation implementing the results of the Uruguay Round of negotiations under the General Agreement on Tariffs and Trade, we are informing the public of the international standard-setting activities of the World Organization for Animal Health, the Secretariat of the International Plant Protection Convention, and the North American Plant Protection Organization, and we are soliciting public comment on the standard-setting activities. ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to www.regulations.gov. Enter APHIS-2021-0077 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2021-0077, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at regulations.gov or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For general information on the topics covered in this notice, contact Mr. Eric Nichols, Director, Trade Support Team, APHIS-IS, room 1627-S, USDA South Building, 14th Street and Independence Avenue SW, Washington, DC 20250; (202) 799-7122.

For specific information regarding standard-setting activities of the World Organization for Animal Health, contact Dr. Paul Gary Egrie, Office of International Affairs, Veterinary Services, APHIS, 4700 River Road Unit 33, Riverdale, MD 20737; (301) 851-3304.

For specific information regarding the standard-setting activities of the International Plant Protection Convention, contact Dr. Marina Zlotina, IPPC Technical Director, International Phytosanitary Standards, Plant Protection and Quarantine (PPQ), APHIS, 4700 River Road Unit 130, Riverdale, MD 20737; (301) 851-2200.

For specific information on the North American Plant Protection Organization, contact Ms. Stephanie Dubon, Acting NAPPO Technical Director, International Phytosanitary Standards, PPQ, APHIS, 4700 River Road Unit 130, Riverdale, MD 20737; (301) 851-2180. SUPPLEMENTARY INFORMATION:

Background

The World Trade Organization (WTO) was established as the common international institutional framework for governing trade relations among its members in matters related to the Uruguay Round Agreements. The WTO is the successor organization to the General Agreement on Tariffs and Trade. U.S. membership in the WTO was approved by Congress when it enacted the Uruguay Round Agreements Act (Pub. L. 103-465), which was signed into law on December 8, 1994. The WTO Agreements, which established the WTO, entered into force with respect to the United States on January 1, 1995. The Uruguay Round Agreements Act amended Title IV of the Trade Agreements Act of 1979 (19 U.S.C. 2531 *et seq.*). Section 491 of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2578), requires the President to designate an agency to be responsible for informing the public of the sanitary and phytosanitary (SPS)

standard-setting activities of each international standard-setting organization. The designated agency must inform the public by publishing an annual notice in the *Federal Register* that provides the following information: (1) The SPS standards under consideration or planned for consideration by the international standard-setting organization; and (2) for each SPS standard specified, a description of the consideration or planned consideration of that standard, a statement of whether the United States is participating or plans to participate in the consideration of that standard, the agenda for U.S. participation, if any, and the agency responsible for representing the United States with respect to that standard.

"International standard" is defined in 19 U.S.C. 2578b as any standard, guideline, or recommendation: (1) Adopted by the Codex Alimentarius Commission (Codex) regarding food safety; (2) developed under the auspices of the World Organization for Animal Health (WOAH)¹ regarding animal health; (3) developed under the auspices of the Secretariat of the International Plant Protection Convention (IPPC, or the Convention) and the North American Plant Protection Organization (NAPPO) regarding plant health; or (4) established by or developed under any other international organization agreed to by the member countries of the United States-Mexico-Canada Agreement (USMCA) or the member countries of the WTO.

The President, pursuant to Proclamation No. 6780 of March 23, 1995 (60 FR 15845), designated the Secretary of Agriculture as the official responsible for informing the public of the SPS standard-setting activities of Codex, WOAH, IPPC, and NAPPO. The United States Codex Office (USCO), in the United States Department of Agriculture's (USDA's) Trade and Foreign Affairs mission area, informs the public of standard-setting activities of Codex, and USDA's Animal and Plant Health Inspection Service (APHIS) informs the public of WOAH, IPPC, and NAPPO standard-setting activities.

¹ The World Organization for Animal Health internationally follows a British English spelling of "organisation" in its name; it was formerly the Office International des Epizooties, or OIE, but on May 28, 2022, the Organization announced that the acronym was changed from OIE to WOAH.

USCO publishes an annual notice in the *Federal Register* to inform the public of SPS standard-setting activities for Codex (86 FR 29987). Codex was established in 1963 by two United Nations organizations, the Food and Agriculture Organization and the World Health Organization. It is the principle international organization for establishing food standards that protect consumer health and promote fair practices in food trade.

APHIS is responsible for publishing an annual notice of WOAH, IPPC, and NAPPO activities related to international standards for plant and animal health and representing the United States with respect to these standards. Following are descriptions of the WOAH, IPPC, and NAPPO organizations and the standard-setting agenda for each of these organizations. We have described the agenda that each of these organizations will address at their annual general sessions, including standards that may be presented for adoption or consideration, as well as other initiatives that may be underway at the WOAH, IPPC, and NAPPO.

The agendas for these meetings are subject to change, and the draft standards identified in this notice may not be sufficiently developed and ready for adoption as indicated. Also, while it is the intent of the United States to support adoption of international standards and to participate actively and fully in their development, it should be recognized that the U.S. position on a specific draft standard will depend on the acceptability of the final draft. Given the dynamic and interactive nature of the standard-setting process, we encourage any persons who are interested in the most current details about a specific draft standard or the U.S. position on a particular standard-setting issue, or in providing comments on a specific standard that may be under development, to contact APHIS. Contact information is provided at the beginning of this notice under FOR FURTHER INFORMATION CONTACT.

WOAH Standard-Setting Activities

The WOAH was established in Paris, France, in 1924 with the signing of an international agreement by 28 countries. It is currently composed of 182 Members, each of which is represented by a delegate who, in most cases, is the chief veterinary officer of that country or

territory. The WTO has recognized the WOAH as the international forum for setting animal health standards, reporting global animal disease events, and presenting guidelines and recommendations on sanitary measures relating to animal health.

The WOAH facilitates intergovernmental cooperation to prevent the spread of contagious diseases in animals by sharing scientific research among its Members. The major functions of the WOAH are to collect and disseminate information on the distribution and occurrence of animal diseases and to ensure that science-based standards govern international trade in animals and animal products. The WOAH aims to achieve these through the development and revision of international standards for diagnostic tests, vaccines, and the safe international trade of animals and animal products.

The WOAH provides annual reports on the global distribution of animal diseases, recognizes the free status of Members for certain diseases, categorizes animal diseases with respect to their international significance, publishes bulletins on global disease status, and provides animal disease control guidelines to Members. Various WOAH commissions and working groups undertake the development and preparation of draft standards, which are then circulated to Members for consultation (review and comment). Draft standards are revised accordingly and are presented to the WOAH World Assembly of Delegates (all the Members) for review and adoption during the General Session, which meets annually every May. Adoption, as a general rule, is based on consensus of the WOAH membership.

The most recent WOAH General Session occurred virtually from May 24 to 28, 2021.

The Deputy Administrator for APHIS' Veterinary Services serves as the official U.S. Delegate to the WOAH. Information about WOAH draft Terrestrial and Aquatic Animal Health Code chapters may be found at

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_international_standard_setting_activities_oie or by contacting Dr. Paul Gary Egrie (see FOR FURTHER INFORMATION CONTACT above).

The corresponding chapters were adopted during the General Session in May 2021.

- Chapter 1.1., Notification of diseases, infections and infestations, and provision of epidemiological information.
- Chapter 1.4.3., *Animal health surveillance*.
- Chapter 1.6., *Procedures for self-declaration and for official recognition by the OIE*.
- Chapter 3.1., Quality of Veterinary Services.
- Chapter 3.2., Evaluation of Veterinary Services.
- Chapter 3.X., New chapter on Veterinary Services.
- Chapter 3.4., Veterinary legislation.
- Chapter 4.Y., New chapter on official control programmes for listed and emerging diseases.
- Articles 4.4.6 and 4.4.7., Zoning and compartmentalization.
- Chapter 7.Z., New chapter on animal welfare and laying hen production systems.
- Chapter 8.Y., New chapter on infection with animal trypanosomes of African origin.
- Article 9.4.5., *Infestation with Aethina tumida (small hive beetle)*.
- Chapter 10.4., Infection with avian influenza viruses.
- Chapter 10.5., Avian mycoplasmosis (Mycoplasma gallisepticum).
- Articles 14.7.3., 14.7.7., 14.7.24., and 14.7.34., *Infection with peste des petits ruminants virus*.
- Chapter 15.2., *Infection with classical swine fever virus*.

IPPC Standard-Setting Activities

The IPPC is a multilateral convention adopted in 1952 to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control. The WTO recognizes the IPPC as the standard setting body for plant health. Under the IPPC, the understanding of plant protection encompasses the protection of both cultivated and non-cultivated plants from direct or indirect injury by plant pests. The IPPC addresses the

following activities: Developing, adopting, and implementing international standards for phytosanitary (plant health) measures (ISPMs); harmonizing phytosanitary activities through adopted standards; facilitating the exchange of official and scientific information among contracting parties; and providing technical assistance to developing countries that are contracting parties to the Convention.

The IPPC is deposited within the Food and Agriculture Organization of the United Nations and is an international agreement of 184 contracting parties. National plant protection organizations (NPPOs), in cooperation with regional plant protection organizations, the Commission on Phytosanitary Measures (CPM), and the Secretariat of the IPPC, implement the Convention. The IPPC continues to be administered at the national level by plant quarantine officials, whose primary objective is to safeguard plant resources from injurious pests. In the United States, the NPPO is the APHIS Plant Protection and Quarantine (PPQ) program.

The 15th Session of the CPM was held virtually from March 16 to April 1, 2021. The CPM adopted the IPPC Strategic Framework 2020-2030, which outlines major work directions for the Convention for the ensuing 10 years and creates a focus group to develop guidance for the framework's implementation by contracting parties.

The CPM adopted the following international phytosanitary standards in 2021. The United States develops its position on each of these draft standards prior to the CPM session based on APHIS' analyses and other relevant information from other U.S. Government agencies and interested stakeholders:

- ISPM 5: Glossary of phytosanitary terms (2018 revisions).
- Revision of ISPM 8: Determination of pest status in an area.
- ISPM 44: Requirements for the use of modified atmosphere treatments as phytosanitary measures.
- ISPM 45: Requirements for national plant protection organizations if authorizing entities to perform phytosanitary actions.

The following phytosanitary treatments were adopted as Annexes to ISPM 28:

Phytosanitary treatments for regulated pests:

- PT 33: Irradiation treatment for *Bactrocera dorsalis*;
- PT 34: Cold treatment for *Ceratitis capitata* on *Prunus avium*, *Prunus salicina*, and *Prunus persica*;
- PT 35: Cold treatment for *Bactrocera tryoni* on *Prunus avium*, *Prunus salicina*, and *Prunus persica*;
- PT 36: Cold treatment for *Ceratitis capitata* on *Vitis vinifera*;
- PT 37: Cold treatment for *Bactrocera tryoni* on *Vitis vinifera*;
- PT 38: Irradiation treatment for Carposina sasakii; and
- PT 39: Irradiation treatment for the genus *Anastrepha*.

The CPM noted that the Standards Committee adopted (on behalf of the CPM)

Diagnostic Protocol DP-29: "Bactrocera dorsalis," as an Annex to ISPM 27: Diagnostic protocols for regulated pests. The CPM also adopted Recommendation R-09, "Safe provision of food and other humanitarian aid."

The IPPC Standards Committee and Implementation and Capacity Development

Committee continued working during the pandemic by virtually approving draft standards for

consultation, selecting experts to expert drafting groups, and addressing pending standard setting

and other plant health initiatives.

IPPC Standard-Setting Initiatives, Including Those Under Development

A number of expert working group (EWG) meetings and technical consultations took place virtually from October 2020 through September 2021 on the topics listed below. These IPPC projects are currently under development and intended for future adoption and publication. APHIS participated actively and fully in each of these working groups. APHIS developed its position on each of the topics prior to the working group meeting. The APHIS position was

based on relevant scientific information and technical analyses, including information from other U.S. Government agencies and from interested stakeholders:

- EWG for revision of ISPM 4: Requirements for the establishment of Pest Free Areas.
- EWG for drafting a new Annex to ISPM 20 (Guidelines for a phytosanitary import regulatory system): "Use of specific import authorization."
- Developing "IPPC Guide to support the implementation of ISPM 15."
- Technical Panel on Diagnostic Protocols.
- Technical Panel on Phytosanitary Treatments.
- Technical Panel for the Glossary.
- Sea Container Task Force.

There are currently 55 trading partners that are connected and actively sharing ePhytos through the system; the United Nations International Computing Centre and the ePhyto Steering Committee are developing and providing training on ePhyto; and preparations are under way to

deploy features allowing industry systems to receive ePhytos. For more detailed information on

The IPPC electronic certification system (ePhyto) solution also progressed in 2021.

the above, contact Dr. Marina Zlotina (see FOR FURTHER INFORMATION CONTACT above).

PPQ actively works to achieve broad participation by States, industry, and other stakeholders in the development and use of international and regional plant health standards, including through the use of APHIS Stakeholder Registry notices² and the APHIS public website. Plant health stakeholders are strongly encouraged to comment on draft standards, documents, and specifications during the consultation periods.

In 2021, 24 draft documents were open for consultation, including standards, phytosanitary treatments, a diagnostic protocol, a specification, outlines for implementation

² To sign up for the Stakeholder Registry, go to: https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new.

tools, and a CPM recommendation. APHIS posts links to draft standards on its website as they become available and provides information on the due dates for comments.³ Additional information on IPPC standards (including the IPPC work program (list of topics⁴), calls for new standards, experts to serve on technical panels and other working groups, proposed phytosanitary treatments, the standard-setting process, and adopted standards) is available on the IPPC website.⁵

For the most current information on official U.S. participation in IPPC activities, including U.S. positions on standards being considered, contact Dr. Marina Zlotina (see FOR FURTHER INFORMATION CONTACT above). Those wishing to provide comments on any of the areas of work being undertaken by the IPPC may do so at any time by responding to this notice (see ADDRESSES above) or by providing comments through Dr. Zlotina.

NAPPO Standard-Setting Activities

NAPPO, a regional plant protection organization created in 1976 under the IPPC, coordinates the efforts among the United States, Canada, and Mexico to protect their plant resources from the entry, establishment, and spread of harmful plant pests, while facilitating safe intra- and inter-regional trade. As the NPPO of the United States, APHIS PPQ is the organization officially identified to participate in NAPPO. Through NAPPO, APHIS works closely with its regional counterparts and industries to develop harmonized regional standards and approaches for managing pest threats.

This critical work facilitates the safe movement of plants and plant products into and within the region. NAPPO conducts its work through priority-driven projects approved by the NAPPO Executive Committee via an annual work program. These projects are completed by

³ For more information on the IPPC draft ISPM consultation: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/international/sa_phytostandards/ct_draft_standards.

⁴ IPPC list of topics: https://www.ippc.int/en/core-activities/standards-setting/list-topics-ippc-standards/.

⁵ IPPC website: https://www.ippc.int/.

expert groups, including subject matter experts from each member country and regional industry representatives. Project results and updates are provided during the NAPPO annual meeting as well as NAPPO governance meetings. Projects can include the development of positions, policies, technical documents, or the development or revision of regional standards for phytosanitary measures (RSPMs). Projects can also include implementation of standards or other capacity development activities such as workshops.

The PPQ Assistant Deputy Administrator, as the official U.S. delegate to NAPPO, intends to participate in the adoption of these regional plant health standards and projects on the work program once they are completed and ready for consideration.

Because of the COVID-19 pandemic, there was no annual meeting held in 2020. Despite the pandemic, NAPPO's Secretariat and its member countries, including regulatory, plant health, and industry officials, continue to actively progress on projects and initiatives under the NAPPO work program, taking advantage of teleconferencing and other virtual meeting tools. NAPPO governance committees, including NAPPO's Executive Committee and the Advisory and Management Committee, as well as expert groups, continue to communicate and meet virtually on a regular basis to actively progress on NAPPO strategic and work program initiatives. The PPQ Deputy Administrator is the U.S. member of the NAPPO Executive Committee. The NAPPO Executive Committee adopted three regional standards between October 1, 2020, and September 30, 2021: Revisions to RSPM 9 (Authorization of labs for phytosanitary testing), Revisions to RSPM 5 (NAPPO Glossary of phytosanitary terms), and Science and Technology Document 7 (Risks associated with the introduction of exotic tussock moth species (Lepidoptera: Erebidae: Lymantriinae) of potential concern to the NAPPO region).

NAPPO's Advisory and Management Committee continued working during the pandemic by virtually approving draft standards for consultation, selecting and onboarding experts to newly launched NAPPO expert groups, and addressing pending work program initiatives.

The NAPPO expert groups, including member countries' subject matter experts, in collaboration with NAPPO's Secretariat, significantly progressed or finalized the following regional standards from October 2020 through September 2021:

- Completed the development or revision and consultation of the following five regional standards: Revision of RSPM 22: Guidelines for construction and operation of a containment facility for insects and mites used as biological control agents; Revision of RSPM 35: Guidelines for the movement of propagative plant material of stone fruit, pome fruit, and grapevine into a NAPPO member country; Revision of RSPM 38: Importation of certain wooden and bamboo commodities into a NAPPO member country; Science & Technology document on Contaminating organisms affecting trade in wood commodities and forestry products; and a Position Document on Asian gypsy moth specified risk periods in Japan, Russia, Republic of Korea, and China.
- Issued via NAPPO's Phytosanitary Alert System: 24 Official Pest Reports from October 1, 2020, to September 30, 2021.

New NAPPO Standard-Setting Initiatives, Including Those in Development

The 2021 work program⁶ includes topics being worked on by NAPPO expert groups and NAPPO's Advisory and Management Committee. APHIS actively and fully participates in the development and approval of the NAPPO work program. The APHIS position on each topic is guided and informed by the best technical and scientific information available, as well as on relevant input from stakeholders. The United States will consider its position on any draft standard after it reviews a prepared draft.

The information in this notice contains all the information available to APHIS PPQ on NAPPO standards or projects under development or consideration. For updates on meeting times and for information on the expert groups that may become available following publication

⁶ NAPPO work program: https://nappo.org/english/governance/work-program.

of this notice, visit the NAPPO website or contact Ms. Stephanie Dubon (see FOR FURTHER INFORMATION CONTACT above).

PPQ actively works to achieve broad participation by States, industry, and other stakeholders in the development and use of international and regional plant health standards, including through the use of APHIS Stakeholder Registry notices⁷ and the APHIS public website. Plant health stakeholders are strongly encouraged to comment on draft standards, documents, and specifications during consultation periods. APHIS posts links to draft standards on its website as they become available and provides information on the due dates for comments.⁸ Additional information on NAPPO standards (including the NAPPO work program, calls for projects, expert groups, the standard-setting process, and adopted standards) is available on the NAPPO website.⁹

For the most current information on official U.S. participation in NAPPO activities, including U.S. positions on standards being considered, contact Ms. Stephanie Dubon (see FOR FURTHER INFORMATION CONTACT above). Those wishing to provide comments on any of the areas of work being undertaken at NAPPO may do so at any time by responding to this notice (see ADDRESSES above) or by providing comments through Ms. Dubon.

Done in Washington, DC, this 7th day of June 2022.

Anthony Shea,

Administrator, Animal and Plant Health Inspection Service.

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https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new.

https://www.aphis.usda.gov/aphis/ourfocus/planthealth/international/sa_phytostandards/ct_draft_standards.

⁷ To sign up for the Stakeholder Registry, go to:

⁸ For more information on the IPPC draft ISPM consultation:

⁹ NAPPO website: http://nappo.org.